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10/559,899	12/06/2005	Herwig Gaston Emiel Van Marck	VIP-0022-USPCT	2752
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PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			SKOWRONEK, KARL HEINZ R	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/559,899

Applicant(s)

VAN MARCK ET AL.

Examiner

KARLHEINZ R. SKOWRONEK

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6 is/are rejected.
- 7) ☒ Claim(s) 6 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
- Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Status

Claim 6 is pending.

Claims 1-5 and 7-16 are cancelled.

Claim 6 has been examined.

Claim 6 is rejected.

Claim 6 is objected to.

Priority

This application is the national stage of PCT/EP04/51084 filed on 10 June 2004 and claims the benefit of US provisional Application No. 60/478,780 filed on 16 June 2003 and European Patent Office application No. 03101687.6 on 10 June 2003.

Specification

Response to Arguments

The objection to the specification is withdrawn in view of the amendment to specification.

Claim Objections

Response to Arguments

The objections to claims 3, 4, 6, and 8 are withdrawn in view the amendment of claim 6 and the cancellation of claims 3, 4, and 8.

Claim Rejections - 35 USC § 101

Response to Arguments

The rejection of claims 3, 4, 8, 10, 14, 15, and 16 are withdrawn in view of the cancellation of the claims.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following rejection is necessitated by amendment of the claims

Claim 6 is drawn to an apparatus that performs a process of predicting resistance of an HIV strain. A review of the specification reveals that the means can be software. The MPEP, at 2106.01, guides that computer programs *per se* are non-statutory. The claims encompass a program *per se* and are non-statutory. Applicant is encouraged to call the examiner to discuss the merits of this case in order to further prosecution.

Response to Arguments

Applicant's arguments filed 18 March 2009 have been fully considered but they are not persuasive. Applicant argues that the amendment to the claim to recite the limitations of a diagnostic system as claimed in now cancelled claim 14 overcomes the rejection under 35 USC 101. The argument is not persuasive because the claim remains non-statutory as drawn to a program *per se*.

Claim Rejections - 35 USC § 112

Response to Arguments

The rejection of claims 3, 4, 6, 8, 10, and 14-16 as indefinite under 35 USC 112 second paragraph are withdrawn in view of the amendments to the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The following rejection is necessitated by amendment of the claims.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 recites the limitation "the censored values" in line 31. There is insufficient antecedent basis for this limitation in the claim.

Claim 6 is unclear with respect to the relationship between step 2 recited in lines 31-68 and step 1 recited in lines 10-30. The metes and bounds of the claim are rendered indefinite by the lack of clarity. Both steps appear to be related to the datasets of genotypes and phenotypes. However, the steps appear to be independent of each other. How the steps are interrelated is not clear. Applicant is encouraged to call the examiner with any questions regarding this rejection.

Claim 6 recites the limitation "the censor values" in line 31. There is insufficient antecedent basis for this limitation in the claim.

Claim 6 recites the limitation "the prediction P" in line 43. There is insufficient antecedent basis for this limitation in the claim.

Claim 6 is unclear with respect to the phrases "for each iteration" and "the next iteration". The metes and bounds of the claim are rendered indefinite by the phrase. The claim does not appear to recite an iterative process.

Claim 6 recites two linear regressions, a linear regression model at line 37 and a linear regression analysis at line 10. It is unclear if the linear regressions are related, and if the regressions are related, how they are related.

Claim 6 is unclear with respect to lines 42-61. It is unclear what active step is being performed in lines 42-61. Line 43 recites using the prediction P. It is unclear from the context of the claim how the prediction P is being used or what is accomplished in the process of using the prediction P.

Claim 6 is unclear with respect to step e at lines 66. It is unclear what applicant intends with the phrase "until the prediction converges". What is being converged upon? When has convergence occurred? The claim fails to provide any measure to define the metes and bounds of the claim with respect to prediction convergence.

Claim 6 is unclear with respect to the variables V and V'. The variables have not been defined in the claim. Their usage without definition makes them unclear. One does not know what the variables mean which makes their relation to the other variables indefinite.

The using step of line 42 in claim 6 is indefinite with respect to the origin of the phenotypic value V_0 . The metes and bounds of the censor is indefinite because lines 31-41, the steps preceding step b, do not employ, indicate the origin, or determination of the phenotypic value V_0 . While the dataset of matching phenotypes and genotypes is

claimed, it is unclear what the relation of the phenotype value V_0 is to the dataset of matching phenotypes and genotypes

As set forth below, claim 6 invokes 35 USC 112, Sixth Paragraph. The MPEP2181 (II) states, "If an applicant fails to set forth an adequate disclosure, the applicant has in effect failed to particularly point out and distinctly claim the invention as required by the second paragraph of section 112." In re Donaldson Co., 16 F.3d 1189, 1195, 29 USPQ2d 1845, 1850 (Fed. Cir. 1994) (in banc). In the instant case, the specification does not provide an adequate disclosure showing the structure, material or acts for these "means-plus-function" limitations, for reasons as set forth below. Therefore, applicant fails to particularly point out and distinctly claim the invention as required by the second paragraph of 35 USC 112, and one skilled in the art would not know what are meant by these "means-plus-function" limitations, and the metes and bounds of the claimed invention are thus unclear.

First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in

the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 6 is directed to a diagnostic apparatus. First, claim 6 recites limitations using the phrase "means for". Second, in claim 6, the recited limitation modifies the phrase "means for" with functional language. For example, line 4 recites "means for obtaining a genetic sequence of an HIV strain". Finally, the "means for" phrases of claim 6 are not modified by sufficient structure, material, or acts for achieving the functions of claim 6. On the basis of the previous three conditions in claim 6, the limitations of claim 6 are considered to invoke 35 USC 112, Sixth paragraph as set forth in MPEP 2181.

35 U.S.C. 112, sixth paragraph states that a claim limitation expressed in means-plus-function language "shall be construed to cover the corresponding structure...described in the specification and equivalents thereof." "If one employs means plus function language in a claim, one must set forth in the specification an adequate disclosure showing what is meant by that language." *In re Donaldson Co.*, 16 F.3d 1189, 1195, 29 USPQ2d 1845, 1850 (Fed. Cir. 1994) (in banc).

In the instant case, the specification fails to set forth an adequate disclosure of what is meant (i.e. a structure) by "means for obtaining", means for "predicting" and "means for identifying " as recited in claim 6

Claim 6 indefinite because the metes and bounds of the claimed means have not been pointed out particularly in the disclosure. The disclosure fails to show a means for obtaining, identifying and predicting. At p. 20-21, the specification provides the example of the means for predicting as a computer means. The specification on p. 21 describes

the means to quantify or calculate are software means. However, the description fails to further describe the material or structure for the means as recited in claim 6. Thus, the claimed subject matter is not "fully and completely" described such that one skilled in the art would have been apprised of what was in applicant's possession at the time of filing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 6 is rejected under 35 U.S.C. 102(b) as being anticipated by Servais et al.

The claims are drawn to a system for quantifying the contributions of mutations to drug resistance of an HIV strain comprising a means for obtaining genetic sequence, means for identifying mutation patterns, and a means for predicting. The limitations of "using a method comprising" as recited in line 9-68 of claim 6, are interpreted as "product-by-process" limitations.

Servais et al. shows a method of quantifying the contributions of mutations to drug resistance of an HIV strain by performing a linear regression analysis on matching genotype-phenotype data to generate a log fold resistance. Servais shows a software means for predicting (p. 242, col. 2), obtaining and identifying (p. 240, col. 2). Regarding the product-by-process limitations of lines 9-68, the prediction produced by Servais et

al. would be indistinguishable from the prediction of claim 6. Therefore, Servais et al. meets the limitations of the claim regarding the "means" recited. Servais et al. shows that a linear mixed effects regression analysis was performed to measure the association between the quantitative predictor variable (the mutations) and the longitudinal data (the resistance phenotype) (p. 241, col. 2). Servais et al. further shows that through the use multiple regressions of the genotype-phenotype data, the additive nature of individual mutation is identified (p. 242, col. 1-col. 2). In figure 2, Servais et al. shows results of the correlation between mutational patterns of HIV protease inhibitors and log fold resistance. Servais et al. shows an embodiment in which the genetic sequence of an HIV strain is obtained via sequencing (p. 240, col. 2). Servais et al. shows an embodiment in which a pattern of mutations is identified that is correlated with a resistance phenotype (p. 240, col. 1-2). Servais et al. shows an embodiment in which the resistance of HIV strains is tested in a patient and is used to select the drug with the lowest predicted fold resistance (p. 246, col. 1).

Claim Rejections - 35 USC § 103

Response to Arguments

The rejection of claims 3, 8, 10, and 14-16 as unpatentable over Servais et al. , in view of Carter et al., and in view of Kempf et al. under 35USC 103(a) are withdrawn in view of the cancellation of the claims.

The rejection of claim 4 as unpatentable over Servais et al., in view of Carter et al., and in view of Michelson et al. under 35 USC 103(a) is withdrawn in view of the cancellation of the claim.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **KARLHEINZ R. SKOWRONEK** whose telephone number is (571)272-9047. The examiner can normally be reached on 8:00am-5:00pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/K. R. S./
Examiner, Art Unit 1631

10 June 2009

/Marjorie Moran/
Supervisory Patent Examiner, Art Unit 1631